S.N. 09/510,937

I. PRELIMINARY REMARKS

Claims 1-28 are pending in the present application. Claims 21-28 were divided out by a restriction requirement in the Office Action of Dec. 30, 2002; claims 21-28 are canceled herein without prejudice as a result of the restriction requirement. Claims 1-9 are allowed, while claims Claims10-20 are rejected under 35 USC 112, first paragraph.

The Abstract of the specification is amended herein to reduce the length to 150 words or less. Basis for the amendment is found in the specification at p. 12, line 32 to p. 13, line 3 and page 9, lines 14 -20.

Applicants hereby request a three-month extension of time. The Commissioner is requested to charge the necessary fees for the Extension of Time to our Deposit Account number 07-1729.

II. APPLICANTS' INVENTION

The present invention relates to a catheter balloon made of tube having a microstructure of nodes and fibrils such as porous expanded polytetrafluoroethylene (PTFE), further including a non-porous coating over the porous microstructure. The coating renders the balloon non-porous and thereby able to contain a desired inflating media (e.g., air or saline fluid). The thinness, flexibility and strength of the construction allow the resulting balloon to be collapsed to a small first diameter for insertion into a vascular conduit to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polyethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons again due to its flexibility, thinness, strength and lubricious materials.

III. REJECTION OF CLAIMS 10-20 UNDER 35 USC 112, FIRST PARAGRAPH.

The Examiner states that the claims do not comply with the written description requirement in that they contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, she notes that "The phrase "the tube being non-porous" is new matter because it is not supported by the specification as originally filed."

Applicants would direct the Examiner to the specification (as filed) at p. 12, lines 32-33 which states that the thin-wall tube of the present invention may be used in a non-porous embodiment as the balloon portion of a balloon catheter. At p. 9, lines 14-20, the specification describes how the porous PTFE film is rendered non-porous with a coating of a continuous layer of adhesive (which is preferably a thermoplastic fluoropolymer adhesive). Accordingly, the use of a non-porous tube of the present invention was supported by the specification at the time of filing.

The Examiner further states that these claims do not comply with the enablement requirement in that th y contain subject matter that was not described in the specification is such a way as to enable one skilled in the art to make and/or use the invention. Specifically, she notes that the specification does not describe the preparation and/or use of inflatable balloons for medical use comprising a non-porous tube with a node and fibril microstructure structure.

The specification describes in detail how a tube is fabricated from thin films. These are typically laid up on mandrels, using either sheets of film or tapes made from such sheets, wherein the tapes are typically helically wrapped about the mandrel surface with overlapping edges to create the tubular form. Please note variously Figures 2-9 which describe (along with the relevant specification text) different ways in which the tube may be laid up. The specification also describes how the resulting tubes are strong, flexible and collapsible (p. 3, lines 4-8), all characteristics that are highly desirable in a catheter balloon. The specification further relates (as noted above; p. 9, lines 14-20) how the porous film is rendered non-porous with an adhesive coating for use as an inflatable catheter balloon. Finally, the specification describes the node and fibril microstructure of the film; see, for example, p. 7, lines 21-24 and Figure 1, which shows a schematic detail of the node and fibril microstructure. Further, US Patents 3,953,566 and 4,187,390 are incorporated by reference (p. 7, line18-20); these patents describe in detail the manufacture of porous expanded PTFE (particularly including films) having a node and fibril microstructure. Other materials having such a microstructure are known to those of skill in the relevant arts (e.g., porous polyurethane). Given the scope of all of these teachings, the person of skill is well-enabled with regard to being able to make a non-porous balloon for medical use from a tube having a node and fibril microstructure. Applicants note (acknowledging that this is not a prior art rejection) that, to the best of their knowledge, they were the first to recognize and reduce to practice the possibility of making a non-porous medical balloon from strong and highly flexible thin films having a node and fibril microstructure by forming tubes of these films and rendering the films non-porous with an adhesive coating.

IV. CITATIONS OF INTEREST

The Examiner noted two patents. The first, US 4,902,292 to Joseph teaches a balloon for implantation within an eye. The balloon may be provided with short segments of tubes joined to the anterior side of the balloon to allow attachment of connective tissue; one material suggested for these short tubes is ePTFE (col. 2, lines 20-23, col. 3, lines 48-57 and Figure 2, ref. no. 2). It is not taught or suggested in any way to use ePTFE for the structure of the balloon.

The second patent, US 4,955,899 to Della Corna et al., teaches an ePTFE tube coated with a non-porous polymer for use as a vascular graft. These tubes are not suggested for use as a catheter

balloon; the thickness range indicated for these vascular grafts (1-10mm, col. 4, line 68-col. 5, line 1) would likely result in inadequate flexibility for any use as an inflatable balloon.

The applicants believe that their claims are in good and proper form and are patentable over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully Submitted,

Wayne D. House

Wayne D. House, 34,623
W. L. Gore & Associates, Inc.
551 Paper Mill Road, P.O. Box 9206
Newark, DE 19714-9206
(928) 864-2574

Date: 4 FEB 2004